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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,582	12/17/2001	Katrien Maria Jozefa Van Laere	BO 44718	5887

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,582	VAN LAERE ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glucose isomerase, does not reasonably provide enablement for any and all enzymes capable of converting an ingested carbohydrate or digestion product thereof into one or more absorbable components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for glucose isomerase, but is not enabled for any and all enzymes capable of converting an ingested carbohydrate or digestion product thereof into one or more absorbable components.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all enzymes capable of converting an ingested carbohydrate or digestion product thereof into one or more absorbable components (assuming that one of ordinary skill in the art could determine a representative selection of such enzymes).

Applicant has only shown in their examples the use of glucose isomerase to treat the claimed uses. With only knowing this one enzyme, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular type of enzyme with which to treat obesity, overweightness, etc. Further, the art is highly unpredictable and to use a specific enzyme to treat a mammal for a specific purpose as claimed does not represent all of the other enzymes contemplated by the claims since enzymes are highly unpredictable by nature and are substrate specific. To expect one type of enzyme to react the same as another type of enzyme in the mammalian body is simply erroneous.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing since it has many antecedant basis problems. For example, "the enteral administration", "the total metabolic caloric value".

Claim 1 is also confusing since it is not clear exactly what the method is being used to do. The use of the "and/or" is confusing. Is the method treating all of these conditions at the same time ?

Claim 5, "the same molecular weight" has no antecedant basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by SU 654682 or JP 408245397.

The patents teach an isomerase administered orally to a patient. All applicant's claims require is that the isomerase is administered to a patient. Since the isomerase is administered to the patient as claimed, then the effects claimed by applicant are inherent to that administration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU 654682 (SU) or JP 408245397 (JP 1) in view of Tsujino and JP 410287575 (JP 2).

The teachings of JP 1 and SU are above. They do not teach to coat the enzymatic preparation and that one of the components of claim 8 are also added.

Tsujino teaches that enzyme compositions are well known to be enterically coated to reduce or prevent the activity of the enzyme by stomach and/or stomach enzymes, see col. 1 and the claims.

JP 2 teaches that *Gymnema* is administered to a patient in an antiobesity formulation.

It would have been obvious to administer the compositions of either SU or JP 1 to a patient having a coating since Tsujino makes it clear that such enzymatic compositions are routinely administered with a coating to prevent the medication (enzyme) from being degraded by other enzymes in the stomach until delivered by the body to the desired part of the body for administration to that desired part of the body.

Further, it would have been obvious to administer *Gymnema* in combination with the isomerase since all of the references (JP 1, JP 2 and SU) teach that isomerase and *Gymnema* are all known to be administered to a patient to treat a disease. Since all the claims require is that a composition be administered to a patient, then this is all the motivation one would need to administer a composition containing these two ingredients.

SU and JP 1 teach that Glucose-6-phosphate isomerase or D-glucose-isomerase are administered to a patient. Thus, it would have been within the purview of the skilled

artisan to use glucose isomerase instead of Glucose-6-phosphate isomerase since it is clear that it would have been within the purview of the skilled artisan to use simply glucose isomerase since glucose isomerase is a well known enzyme to be administered to patients to treat conditions.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carey et al. '508 or Carey et al. '358 in view of Tsujino, SU 654682 and JP 410287575 (JP).

The Carey references teach that isomerases are administered to a patient to treat conditions. They do not teach to coat the isomerases, that the isomerases are glucose isomerase, that the administration is oral or that one of the components of claim 8 are also added to the enzymatic composition.

The teachings of SU are above.

Tsujino teaches that enzyme compositions are well known to be enterically coated to reduce or prevent the activity of the enzyme by stomach and/or stomach enzymes, see col. 1 and the claims.

JP teaches that *Gymnema* is administered to a patient in an antiobesity formulation.

It would have been obvious to administer the compositions of either of the Carey references to a patient having a coating since Tsujino makes it clear that such enzymatic compositions are routinely administered with a coating to prevent the medication (enzyme) from being degraded by other enzymes in the stomach until

delivered by the body to the desired part of the body for administration to that desired part of the body.

Further, it would have been obvious to administer *Gymnema* in combination with the isomerase since all of the references (Carey refs., SU and JP) teach that isomerase and *Gymnema* are all known to be administered to a patient to treat a disease. Since all the claims require is that a composition be administered to a patient, then this is all the motivation one would need to administer a composition containing these two ingredients.

Since SU teaches that glucose isomerase is orally administered to a patient to treat a condition, it would have been within the purview of the skilled artisan to use glucose isomerase instead of isomerase since it is clear that it would have been within the purview of the skilled artisan to use glucose isomerase since glucose isomerase is a well known enzyme to be administered to patients to treat conditions. It further would have been obvious to orally administer the isomerase since the isomerase is known to be used to be orally administered as is also evidenced by SU.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Examiner
Art Unit 1651

MVM
September 23, 2002